g5234d

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

February 28, 2005

VIA FEDERAL EXPRESS

Joel Knox, President
Inland Seafood Corporation of America
1222 Menlo Drive, NW
Atlanta, GA 30318

Warning Letter
05-ATL-08

Dear Mr. Knox:

On January 25 - 28, 2005, the United States Food and Drug Administration (FDA) conducted an inspection of your subsidiary, Bimini Island Seafood (Bimini Island), a seafood processing facility located at 1238 Menlo Drive, NW, Atlanta, Georgia. During that inspection, our investigators documented serious deviations from the seafood Hazard Analysis and Critical Control Point (HACCP) regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123). In accordance with 21 CFR § 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or to otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, Bimini Island's ready-to-eat seafood salads and dip products are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and the seafood HACCP regulations through links in FDA's home page at *www.fda.gov*.

The deviations of concern are as follows:

1) You must conduct, or have conducted for you, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a written HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR §§ 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR § 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, Bimini Island's HACCP plan for seafood salads and dip products does not list the food safety hazard of undeclared sulfiting agents for those products containing shrimp and/or lobster, and the hazard of histamine formation for those products containing tuna, a scombroid fish.

2) You must have a HACCP plan that, at a minimum, lists the monitoring procedures for each critical control point (CCP), to comply with 21 CFR § 123.6(c)(4). However, Bimini Island's HACCP plan for seafood salads and dip products lists a monitoring frequency at the "Finished Storage" CCP that is not adequate to control the safety hazard of pathogen growth and toxin formation. Your HACCP plan requires that a visual check of the temperature in the finished storage area be conducted two times a day. In the absence of continuous temperature monitoring/recording or an alarm system, the two daily temperature checks are insufficient to ensure compliance with the listed critical limit.

   In addition, our investigators observed finished ready-to-eat seafood products being stored in the "cooked product room" and/or the dry ingredient storage area, both of which appear to lack adequate temperature monitoring/control.

This letter may not list all the deviations at Bimini Island. You are responsible for ensuring that the Bimini Island processing plant operates in compliance with the Act, the seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may initiate regulatory action without further informal notice. Such actions may include the initiation of a seizure action against Bimini Island products and/or an action to enjoin Bimini Island from operating.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation, such as copies of HACCP plans and HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,

Mary Woleske

Mary H. Woleske, Director
Atlanta District